Official Trial Title
Assessing a Novel Virtual Environment That Primes Individuals Living With AD/ADRD to Accomplish Activities of Daily Living

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Document:
Protocol and Statistical Analysis Plan

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Protocol (and included IX. Statistical Analysis Plan)

Protocol Title: 1R43AG071102-01A1 Assessing a Novel Virtual Environment that Primes Individuals Living with AD/ADRD to Accomplish Activities of Daily Living.
Protocol Version: 3.6
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I. Abstract - Summary of the study background, aims, and design.

Central themes in person-centered care are dignity/respect/choice for the care recipient.

This SBIR Phase l clinical study is a minimal risk study that focuses on how the new technology, DevaWorld (DW), can support and amplify these principles, while assisting care staff.

DevaWorld is an interactive assistive technology developed with user-centered design principles, mirroring fifteen evidence-based non-pharmacological interventions for people living with Alzheimer's disease and its related dementias (AD/ADRD). Built with a game engine and deployed on a tablet device, DevaWorld is a purpose-built virtual world depicting activities of daily living (ADLs). It contains interactive engagement stimuli, including customized digital artifacts that hold meaning to the person.

During a DevaWorld session (DWS), both the care-partner and care-receiver (dyad) are active participants. Preliminary evidence shows that DWS sessions support the psychosocial wellbeing of people living with dementia (PLWD). Informally collected data lead us to the current study, in which we measure the impact of DevaWorld ADLs on actual ADLs. We hypothesize that undertaking ADL-related virtual activities will support completions of actual ADLs, thereby increasing effectiveness and improving care outcomes.

The aims of this mixed-method, single-arm study are to (1) demonstrate the feasibility (tolerability and acceptability) of DevaWorld within daily routines, and (2) evaluate the effectiveness of DevaWorld sessions in preparing PLWD for specified ADLs. Endpoints are: evidence of the dyads' acceptance of DevaWorld, a reduction in ADL-related care challenges compared to baseline, and overall durations of time spent on the ADLs compared to baseline.

II. Background and Significance

The current environment that is the basis for the proposed research, including a presentation of the problem, a critical evaluation of current knowledge and a description of how this proposal will enhance this knowledge.

The significance of improving ADL capacity has a cascading effect across the entire dementia care ecosystem. Research correlates the inability to accomplish ADL with lower quality of life (1, 2) and increased health care costs (3). ADL dependency requires more resources, and the risk of increased morbidity and mortality is higher than those who are ADL-independent (4) (5) Dependency can be the direct result of insufficient capacity to provide adequate daily assistance to care-recipients, accounting for 49% of the total direct costs associated with Alzheimer's disease and related dementias (AD/ADRD) (6). Care staff are curtailed by time pressures and inadequate training, which diminish PWLD's autonomy and dignity leading to lower self-esteem and reduced value in others' eyes (7–9). Inadequate attention to personhood can evoke confusion, fearfulness, disorientation, aggression and apathy in the person impacted by dementia (10, 11), adding to care staff stress and job dissatisfaction (12). Staff departures and costly turnovers often follow, further eroding the care services sector (13). Scales & Lepore (2020) compute that from 2018 to 2028, the workforce is expected to add 1.3 million jobs, and an additional 6.9 million jobs will become vacant as existing workers leave the field or exit the labor force. These figures indicate the pressing need to reduce staff stressors to forestall what they describe as "an escalating national crisis of unmet need for long-term services and supports" (p.2). Combined, these factors contribute to the $305 billion currently paid by Medicare for dementia care (14). However, this figure does not fully scope the magnitude of the socioeconomic burden of AD/ADRD, which AARP surmises will be unsustainable as the AD/ADRD population grows (15).

By deploying our novel site of virtual environments, DevaWorld, which contains ADL-related engagement stimuli, this proposal will advance understanding of how technology-based interventions can mitigate negative responses to ADLs for increased satisfaction within the dyad, greater effectiveness and better care outcomes. This evidence will be used to support DevaWorld's value within the long-term care services sector and advance our case as an FDA-credentialed digital therapeutic.

III. Study Aims

The purpose of the study, including identification of specific primary objectives/hypotheses.

The purpose of the study is to show evidence of DevaWorld's value in long-term care settings. Our primary objective is to show that DevaWorld's virtual ADLs support real-world ADLs resulting in more manageable, more effective ADL completions. We hypothesize that a DWS reduces behavioral responses and care partner stress to achieve this outcome.

The aims are to:
(1) demonstrate feasibility (tolerability and acceptability) of DWS within the dyad
(2) evaluate the effectiveness of DevaWorld sessions for preparing PLWD for specified ADLs

IV. Administrative Organization

Mentia DTx, Inc. is the grantee. It is the entity responsible for the research and development of DevaWorld. Mentia DTx provides project management and data management services. The PI, Mandy Salomon PhD, is a Mentia DTx employee.
The participating study sites with IRB approval will be
(1) assisted livingcommunity for older adults, 90% of whom experience cognitive decline.
(2) assisted living memory care community or similar.

V. Study Design

a. Experimental design of the study

This mixed-methods single-arm eight-week feasibility study (Phase I) monitors approximately forty residents and their usual care staff across two residential care communities. We will use both quantitative and qualitative methods will be used to produce data sets for analyses.

b. Study population general description

The study population is long-term care residents aged 65 years and older, with moderate to moderate to severe dementia, according to the Global Deterioration Scale for Assessment of Primary Degenerative Dementia (GDS) (Reisberg, 16).

c. Sample size determination and power analyses

We target a 95% confidence level for our study. For a confidence interval of 15%, the sample size is 32. A 15% confidence level is sufficient for a feasibility study.

d. Study outcomes/endpoints

The study outcome will be a body of evidence that supports our hypothesis: that interactions with ADL content inside the graphical interactive virtual world, DevaWorld, supports completions of actual ADLs.

DevaWorld's feasibility (Aim 1)

Successful primary outcomes are >55% DWS-participation rate and a statistically significant difference between assessments of DWS-participation and non-participation, indicating tolerability and acceptability of routine DWS.

DevaWorld as an assistive tool for preparing and completing ADLs. (Aim2)

Successful secondary outcomes are:

- a reduction in ADL-related care challenges compared to baseline
- reduced time spent on ADLs compared to baseline
- a reduction in negative response behaviors associated with the ADL
- greater interest in the ADL
- a positive shift in care staff attitudes

VI. Study Procedures

a. Subject Selection Procedures

i. Sampling plan including Inclusion/Exclusion criteria

We will use convenience and purposive sampling (22) to recruit residents from our testsites in the United States.

We determine our sample size to be 40 in anticipation of 20% dropout rates, which concurs with similar studies. We estimate that a sample size of 32 would allow us to determine the tolerability, acceptability, and feasibility of DW sessions based on similar pilot studies conducted for technological interventions in Alzheimer's disease (18).

ii. Recruitment Procedures

1. *Where will recruitment occur?*
   - At the test sites.
2. *Where and when will consent be obtained*?
   - At the sites during a meeting after being interviewed or a week later.
3. *Who will obtain consent?*

   PI and Project Manager
4. *What is the advertising plan, if applicable?*
   - N/A
5. *What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?*
   - Zoom/meeting; Information statement and informed Consent documents

iii. Screening Procedures

1. *What procedures are required for screening?*
   - Residents: Discussions with clinical care team and a review of resident's profiles and case notes. We work with care staff to identify resident-participants and their families who have shown a willingness to be involved in previous studies, or who are generally open, enthusiastic and curious to new projects.
   - Staff: Discussion with clinical care team to determine suitable care staff. We work with them to identify resident-participants and their families who have shown a willingness to be involved in previous studies, or who are generally open enthusiastic and curious to new projects.

2. *What is the screening schedule (number of visits, length of visits)?*
   - Clinical team (2 hours)
   - One preliminary meeting with care staff (1 hour).

3. *Which screening tests/procedures are standard and which are for research purposes only?*
   - N/A

b. Consent Process and Timing.

i. Process

Residents

We initiate the consent process by giving residents the opportunity to review the consent from. Proxies, where needed, will receive the consent form as well. (19)

All proxies and residents will be given an opportunity to attend a virtual face-to-face question and answer session, and will be invited to contact the PI directly with further questions.

- Timing for the consent process:

After proxies or residents, as appropriate, have shown comprehension, they will then be permitted to sign the consent form.

Care staff

We initiate the consent process by consulting with the clinical care teams to make a short list of staff who they believe to be well suited to the study.

- Are regular professional care employees
- Are familiar with the care routines

Staff-participant candidates will be invited to attend a virtual or face-to-face question and answer session, and will be invited to contact the PI directly with further questions.

- Timing:

Consent letter to be provided at the Q&A session, after which attendees will be asked to show comprehension. They will then be permitted to sign.

ii. Who is conducting the consent process and their qualifications?

PI: Mandy Salomon, PhD and the Project Manager, Algis Leveckis, in collaboration with care team members at the sites.

iii. If there will be a waiver of consent or of documentation, explain the rationale andregulatory section for the waiver. N/A

- N/A

iv. Describe how much time will be given to potential subjects to consider participation.

- One week to consider
- Opportunity for subject/proxy to attend a Q&A session
- Opportunity for participants to contact the PI with any further questions
- After assurance of comprehension, opportunity to sign consent form in person, or by electronic signature.

c. Study Assessments and Activities

i. Description of participants and what they will be asked to do:

Residents

Approximately forty residents will be enrolled of any age, gender, or cultural background with a target (though not required) of equal male and female participation. The subject will have a diagnosis of AD/ADRD, or symptoms of an undiagnosed AD/ADRD as observed by professional care staff and confirmed by the head of clinical care. We will neither include

nor exclude participation based on cognitive test scores, however, participants will be giventhe MMSE test (20) at baseline. Anonymized scores may be referenced in post-study discussions. The participants will have had challenge(s) completing one or more ADLs in the previous month, as discussed at staff meetings, referenced in care plans, or observed/experienced by direct care staff. Ineligible residents are those with significant

non-AD/ADRD neurological, psychiatric, or physical impairment or those who are totally dependent upon others for ADLs.

Other specifications:

- Understand English or Russian.
- Are verbal
- Can sit comfortably for at least 15 minutes in a chair/wheelchair at a table or propped up in bed or princess chair with a tray table
- Are not known to be in pain
- Have good vision, or good corrected vision (i.e., glasses)
- Have good hearing, or good corrected hearing (i.e., aids)
- May sometimes have anxiety or agitation when undertaking ADLs.

Exclusion criteria

- Persons subject to a legal protection order
- Current or planned participation in other research involving neuropsychological evaluations and/or drug trial, up until the end of the current study.
- Informed consent not signed
- Compatible caregiver not found

Staff

Staff are experienced and motivated; are employed at the test site; assist with ADLs will have ADL care experience with residents prior to the study. Their role is to support the participant during a DWS and help them have an optimal session with the app. Staff will receive training on this. After the DWS, staff will assist the resident with their usual ADL routine at times suited to the resident. They will also fillout reports each day.

ii. List and describe each of the study procedures, assessments, and activities.

- Initiation session with staff to outline baseline study protocol.

- In the first two weeks of the study to establish baseline, dyads will undertake usual ADL care, i.e., without the DevaWorld Session (DWS) intervention. Staff schedule during baseline:

Mon 40m	Tue 40m	Wed 40m	Thu 40m	Fri 40m
Res A Mouth Care	Res A Mouth Care	Res A Mouth Care	Res A Mouth Care	Res A Mouth Care
Res B Mouth Care	Res B Mouth Care	Res B Mouth Care	Res B Mouth Care	Res B Mouth Care
Res C Mouth Care	Res C Mouth Care	Res C Mouth Care	Res C Mouth Care	Res C Mouth Care
Res Mouth Care	Res Mouth Care	Res Mouth Care	Res Mouth Care	Res Mouth Care
Reporting before end of shift				

- Following baseline and prior to the intervention phase, participating staff will take part in group training, with extra support as needed.

- During the intervention phase, a period of six weeks, the same dyads (or as close to same as is practical) will be assigned a schedule incorporating DWS followed by the same ADL routine as baseline.

- Each resident-participant will have two DWS per week. Staff-participants will spreadthis load across their shifts, averaging eight DWS sessions per 5-day week. We anticipate that session durations will average five minutes with variability according to resident-participants' individual interest levels on a given day. Staff schedule during study:

<table>
<tr><th>Mon
1h 10m</th><th>Tue
55m</th><th>Wed
1h 10m</th><th>Thu
55m</th><th>Fri
1h 10m</th></tr>
<tr><td rowspan="2">Res A
DWS</td><td>Res A
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DWS</td><td>Res B
Mouth Care</td></tr>
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<tr><td colspan="5">Reporting</td></tr>
</table>

- <u>Procedure for running a DWS</u>

  - Initiating a session:
    Prior to the ADL, the dyad will sit in a quiet nook or the resident's bedroom with appropriate lighting. The care staff will ask the resident if they are comfortable (e.g. need a drink, need to go to the toilet, is comfortably dressed, has glasses and hearing aids in place).

    To initiate the session, the care staff will open DevaWorld on the tablet device and invite resident to join.

    Consent/No consent:
    As the app opens, the care staff will obtain verbal consent (resident uses affirming, positive words or sounds) or non-verbal consent (resident smiles/nods/leans toward the tablet/touches care staff in a positive way/agrees to touch the screen either independently with care staff's support).

    If no consent, the caregiver will reapproach in 3-5 minutes, again check if the

person is comfortable, and make any adjustments to improve comfort. Care staff will seek consent again. If consent is not given a second time, the DWS will be dropped and the usual ADL routine will begin.

Ongoing Participation or Refusal:
Staff will record the resident's attitude to the DWS in their daily report. The research team will review these reports daily.

Refusal may be communicated verbally (using negative or anxious words or sounds) or non-verbally (shrugging, shaking head, pushing the tablet away, refusing to put hand to the tablet, not permitting the care staff to hold their hand to support screen tapping, turning their body away, looking away from the app, passive disinterest

If a resident-participant decides that they no longer want to be involved in the study, not just the DWS session for the day, they will be offered DWS sessions daily. After 7 consecutive days of refusals, they will be withdrawn from the study.
(Guidance on the Process Consent method is covered during training and isdescribed below.)

- Plan for 5 mins per session
- Upon consent, care staff initiates the DWS and guides the resident to the part ofDevaWorld where the interactive ADL will be explored
- Following the resident's lead in pace and interest, the dyad focuses on helping theDevaWorld characters (male or female) to manage self-care activities in
  DevaWorld's bathroom and getting him/her ready for bed.
- The session will end when the resident seems ready
- Upon completion of a session, the care staff assists the resident, if needed, to selectan emoticon on the end screen before ending the DWS.
- After completing the DWS, the care staff will initiate the planned ADL task, andobserve their resident's interactions, cooperation, mood and any behavioral responses.

- Process Consent (21). This method is used during DevaWorld sessions.
  - Staff participant checks consent prior, during and after DW session.
    If Subject indicates their withdrawal of consent, Staff stops and lets the resident withdraw before or during the activity
  - If the resident no longer wants, or is no longer able, to be involved.
    The staff observes residents wishes (verbally or non-verbally) to guide the next steps. Staff then informs the researcher.
  - Depending on the situation, it may or may not be appropriate to ask the resident again later if they would like the opportunity to get involved., The caregiver will reapproach in 3-5 minutes, again check if the person is comfortable, and make any adjustments to improve comfort. Care staff will seek consent again. If consent is not given a second time, the DWS will be dropped and the usual ADL routine will begin.

- <u>Assessments, tools</u>
  Reliability
  A staff champion (internal) will be appointed to oversee adherence to the study and liaise with the research team about any obstacles they notice along the way, such as

absenteeism or the need for extra training. A research assistant (external), in the role of reliability observer, will be assigned to track data, checking for reporting compliance and anomalies. The PI will review data week-by-week to ensure the study design continues to fit its purpose.

- Data collected at Baseline

Residents

- **Demographic variables:** Gender, age, race, ethnicity, marital status, socioeconomic status, languages spoken/language preference.
- **Stage of dementia** The Global Deterioration Scale for Assessment of Primary Degenerative Dementia (GDS) (16)
- **Cognitive Function:** The Mini Mental State Exam (MMSE) (20).
- **Functional stage** (Functional Assessment Staging Tool (FAST), (22): The FAST is used to describe the stages of dementia and employs a seven-stage system based on one's level of functioning and ability to perform daily living activities.
- **Time since admission** to facility (in months) {subtract date of admission from date of assessment).
- **Quality of life:**
  -DEMQOL/DEMQOL-proxy (23).
- **Response Behaviors**
  - The Neuropsychiatric Inventory (NPI): Assessing psychopathology in dementia patients. (24).
- **ADL capacity**
  Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory (ADCS-ADL) 19- item inventory to assess activities of daily living for clinical trials in Alzheimer's disease. (25).

Care Staff

- **Demographics:** Age, gender, race, ethnicity, number of years of schooling and highest degree obtained, US or foreign born; languages spoken/language preference, marital status, currently or previously the primary informal caregiver of a person with dementia (a predictor of job satisfaction (26). Job background: Years as a CNA, years working for this employer, employed full or part time.
- **Burnout:** Copenhagen Burnout Inventory (27).
- **Sense of Competence**: Sense of Competence in Dementia Care Staff (SCIDS) (28).
- **Attitudes towards People with Dementia:** Approaches to Dementia Questionnaire (ADQ) (29).
- **Job Satisfaction**: Minnesota Satisfaction Questionnaire, Short-form (30).

Baseline data for Usual ADLs – No Intervention

- Staff's usual reporting at the end of each shift.
- Additional: the survey webpage.
  - Subject name
  - Time: start of ADL and stop ADL
  - ADL checklist: toothbrushing, grooming, face wiping, taking medications
  - Was the activity completed?
- Subject's responses to the ADLs (multiple choice and text box)
  - Subject's autonomy to the activity (Likert scale of 1- 4)
  - Subject's attitude to the activity (Likert scale of 1- 4)
- At the end of the baseline studies, staff complete an ADCS-ADL score sheet for

each of their residents to provide longitudinal comparisons (31).

- Data collected during the Intervention phase

  Reporting on The DevaWorld App's Feasibility (Aim 1)
  - The DW app captures screen interactions, durations, end-of-session emoticons for self-assessment and end-of-session comments (choice of spoken or text input).
  - The tablet's built-in camera records the dyad's expressions and exchanges during the session. These videos support analysis of engagement and reaction, and create a unique data set for developing speech emotion recognition system for future product upgrades.
  - Occasionally research staff may also capture video and audio using an iPhone during DWS for capturing other nuances of the dyad engagement.
  - In addition, at end of shift, staff complete a web-based questionnaire that
    - measures tolerance and acceptance of DevaWorld
    - records observations of resident's post and pre-post disposition
  - Questions are a mix of multiple choice, 5-point Likert scales and free text
  - Computers are located at the nurse station.

  Reporting on Usual ADLs, following Intervention (Aim 2)
  - Staff's usual reporting at the end of each shift.
  - Additional: the survey website.
    - Subject name
    - Which ADLs were done (checklist)?
    - Time taken to start and finish
  - Subject's responses to the ADLs (multiple choice and text box)
    - Autonomy to the activity (Likert scale of 1- 4)
    - Attitude to the activity (Likert scale of 1- 4)

- End of study
  - Residents will repeat Quality of Life and Response Behavior outcome measures (same ones as used in Baseline**).**
  - Participating staff will complete an ADCS-ADL scores sheet for each of their residents to provide longitudinal comparisons
  - Participating staff will undertake a 5 min exit interview at the conclusion of the trial.The interview will supplement and facilitate the interpretation of quantitative data gathered during including any post and pre-post concerns over the course of the study, which may provide further insights (32).

iii. Explain training of individuals performing procedures

Training sessions will take place after baseline studies as knowledge transfer before or during baseline may introduce a bias. Staff will be shown the DevaWorld app and how to work optimally with it.

This will be a hands-on lesson with staff sharing one device between them alternating staff and resident roleplays. Mentia's instruction guide, 'How to get the most out of your DevaWorld Session' and training videos will be the basis of the training. Staff will also be guided on environmental aspects such as thebest time and place, how to set up and introduce the DWS, and how to transition from the session to the ADL.

Each site will have a highly-trained internal champion, who will attend training and provide on-going support to staff throughout the study

Agenda for group training session.

- Introduction to the study aims and their critical role.
- Instruction on DevaWorld usage with a focus on the ADL content.
- A short review to identify any knowledge gaps.
- Follow-up sessions will be scheduled as needed.
- Break
- Study Protocol covering consent, scheduling, reporting, risks
- 5-minute pre-intervention interview so that we can learn about any potential barriers to participation in, or adherence to, clinical trial requirements.

iv. Be clear about the difference between what is standard (if there were no evaluation study) and what is done specifically for the study.

As a single arm study, the distinction we believe the distinction will be clear, i.e., care shift with usual care and the intervention, and care shift usual care and no intervention.

During the 6-week intervention part of study; on both intervention and no-intervention days, staff are encouraged to modify their practiceaccording to any insights they derive from the study. They will be asked to note any modifications in their end-of-shift report.

VI. Privacy and Confidentiality

The attached DSMP and Informed Consent documents answer the following

a. What steps will be taken to protect the subject's privacy?
b. What steps will be taken to protect the confidentiality of the data obtained?
c. Who will, or may in the future, have access to data?
d. Is there a destruction date or event for identifiable data?

VII. Safety Monitoring Plan

The attached DSMP and Informed Consent documents answer the following

a. Definition of adverse events, serious adverse events
b. What procedures will be used to monitor subject safety?
c. Who will identify, document, and report adverse events?
d. What is the frequency for review of summarized safety information and who will perform the review (e.g., safety monitoring board)?
e. What are the stopping rules with regard to effectiveness and safety?

IX. Analysis Plan

Describe statistical analysis methods as appropriate. For example, will intention-to-treat methodology be used in the analysis? Will there be any sample stratification?

- Thematic and sentiment analysis of tablet-recorded spoken and visual exchanges during DWS and post-session comments
- Statistical and text analyses of questionnaire responses
  - Statistical Analysis Plan
    - Assessment inventories with scores on the inventory's scale
    - Measuring mean value and standard deviation for the group
    - Complete a superiority statistical test
    - P-values calculated by t-test, 1 sided

HIPAA-compliant data capture software; eg REDCap, will be used to create the database and analyses. https://www.project-redcap.org/

Data will be reported graphically or with summary measure (e.g., means and standard errors or median and 95% confidence intervals), and subjected to statistical analysis when appropriate.
Completion rates and grades scores will be presented as proportions and percentages.

ADCS-ADL scores will be compared from end of baseline to biweekly scores to the end of intervention and may be analyzed using a paired Student's t-test or the Wilcoxon signed-rank test if the data are not normally distributed.

Completion rates will be the percentage of all dyads who complete the entire eight weeks of study. The ratio of positively graded scores per dyad will be calculated to obtain the level of satisfaction of dyads and indicate the acceptability of DWS.

Aim 1: Successful primary outcomes are >55% completion rate and a statistically significant difference between assessments of completers and non-completers, indicating tolerability and acceptability of routine DWS.

Aim 2: The secondary outcome is to determine the feasibility of DevaWorld as an assistive tool for preparing and completing ADLs. Improved dyad outcomes are less time to complete ADLs, a reduction in negative response behaviors associated with the ADL, greater interest in the ADL, Care staff indicates tasks are easier than before.

Outcomes measures for baseline and intervention will be the same. As the score sheets cover a broader range of ADLs than those depicted in DW, overall and individual ADL scores will be analyzed and subjected to statistical tests. Our null hypothesis will be no statistical differences between ADL scores during the intervention and baseline phases

X. Timing

From the start of baseline to when the study ends will be about 2 months.

XI. Literature Cited

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